REMARKS

A. Status of the Claims / Claim Amendments

In the Office Action of March 19, 2008:

(1) Claims 19, 20, 23, 26, 28, 30-33, 101, 102, 105, 108 and 110-114 were treated as being withdrawn from further consideration because they were considered to be outside the scope of the earlier election of species.

(2) Claims 35-90 were previously canceled and remain canceled.

(3) Claims 103, 106, 107 and 109 were objected to on the ground of lack of antecedent basis for particular claim terminology.

(4) Claim 100 was objected to on double patenting grounds relative to Claim 99.

(5) Claims 1-18, 21, 22, 24, 25, 27, 29, 34, 91-100, 103, 104, 106, 107, 109 and 115 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,719,773 (Boucher '773) in view of U.S. Pat. Publ. No. 2001/0007938 (Long '938).

In this Amendment and Response, the claims that the Examiner treated as being "Withdrawn" have been indicated as "Withdrawn," but have not yet been canceled. Applicants respectfully request, however, that the Examiner reconsider her position that these claims are not within the scope of the elected species.

The objected-to claims, Claims 103, 106, 107 and 109, have been amended (or the claims on which they depend have been amended) to address the antecedent basis issues.

The dependency of Claim 100 has been corrected, which is believed to obviate the double patenting objection.

Independent Claims 1 and 91 have been amended to more clearly recite the positioning of the spring element relative to the tube lumen and the fluid inlet. In addition, new Claims 116-145 have been added. These claim amendments and new claims are fully supported by Figs. 17A through 21C of the application and the related description of these drawings at page 20, line 21 to page 22, line 22 and also at page 37, line 4 to page 40, line 2 of the Specification. Upon request, Applicants agree to specifically identify the support for any portions of the claim amendments or the new claims.

Applicants respectfully request reconsideration of the Sec. 103 rejection based on the claim amendments and the following Remarks.

B. The Sec. 103 Rejection

As noted above, all of the pending claims have been rejected under 35 U.S.C. §103(a) as being unpatentable over Boucher '773 in view of Long '938.

1. General Comments

The pending claims are directed to a particular elected embodiment of the invention as represented by Figs. 17A through 21C of the application. In this elected embodiment, the balloon tensioning and/or balloon wrapping device comprises a combination of a rod element in association with a spring element which, operating together, can apply tensioning and/or wrapping forces to a balloon element at the end of a catheter apparatus.

As described in the application, the combination of the rod and the spring element operating cooperatively results in apparatus advantages and operational synergies that are not realized using only one element or the other.

Boucher '773 teaches the use of an externally manipulatable stylet to tension and/or wrap a balloon element to which the stylet is attached at its distal end. However, as the Examiner acknowledges at page 7 of the Office Action, "Boucher et al fail to teach or disclose a spring element with particular properties as part of the balloon tensioning and/or wrapping device." The Examiner has cited Long '938 to make up for this admitted deficiency of the Boucher '773 reference.

2. Long '938 Does Not Teach A Spring Element as Part of an Assembly as Recited in the Claims

Claims 1 and 91 have been amended herein to more clearly recite the structural relationships between the spring element and the other components of the claimed assembly. Independent Claim 1 now recites that the "spring element [is] located at the proximal end of the assembly proximal of the fluid inlet and fluidically isolated from the tube lumen...." Independent Claim 91 recites comparable structure.

No comparable structure is shown or described by Long '938. Indeed, in the context of Long '938, recited structural features such as "proximal of the fluid inlet" and "fluidically isolated from the tube lumen" cannot be given any reasonable meaning because the Long '938 apparatus is so completely different from and unrelated to the present invention.

In general terms, Long '938 is directed to a medical instrument that can be inserted into a human body by means of a catheter (specifically, an endoscope) tube. However, the specific part of Long '938 referenced by the Examiner relates only to a particular portion of a medical device designed to be inserted through a catheter. Although the Examiner does not identify the section of Long '938 being relied upon, the reference numerals listed in the Office Action relate to Fig. 5 of Long '938.

Referring to Fig. 5 of Long '938, the component that is illustrated here (reference numeral 70a) is identified as a "balloon electrode 70a" which is located "at the distal end of flexible elongated tube 71...." (paragraph [0047]). This same paragraph of Long '938 further teaches that: "Both the balloon electrode 70a and the flexible elongated tube 71 are filled with a conductive fluid 74 ... for the conduction of RF energy to tissue in contact with the balloon electrode 70a. To ensure contact between the balloon electrode 70a and the diseased inner lining of the esophagus, the balloon electrode 70a has an expandable sleeve 75 that is expanded by pressurizing the conductive fluid 74."

As explained at paragraphs [0051] and [0052] of Long '938, contained inside expandable sleeve 75 there is a "non-conductive semi-rigid support 73" which in "the illustrated embodiment is a non-conductive spring...." But, "support 73" is neither designed nor intended to axially compress or decompress. Paragraph [0052] of Long '938 makes it clear that the actual purpose of "support 73" is to "deflect to reduce possible tissue damage impact trauma ... [a]dditionally, the non-conductive semi-rigid support 73 bends the balloon electrode to the shape of the lumen or cavity and around corners when maneuvering a torturous lumen or passage."

In order to try to make the Long '938 reference fit the needs of her rejection, the Examiner has identified the "hollow spacer tube 78" of Long '938 as the "rod" recited in the claims, and she has argued that "compressing rod 78 toward end 80 compresses the spring and would elongate balloon 75 as spring 73 is semi-rigid." This construction of Long '938, however, is patently impossible and suggests that the Examiner failed to carefully read this reference.

Long '938 teaches (paragraph [0050]) that "hollow spacer tube 78 is fixed longitudinally within the flexible elongated tube 71." Long '938 also teaches (paragraph [0049]) that "[t]he expandable sleeve 75 is hermetically attached ... to the flexible elongated tube 71 by a proximal retaining sleeve 76." Thus, compression of the "semi-rigid support 73" of Long '938 by moving Long's "spacer tube 78" is not physically possible.

Furthermore, the "semi-rigid support 73" of Long '938 is positioned at the distal end of the Long apparatus – indeed, balloon electrode 70a, which contains element 73, must be inside the human body to function. By contrast, the spring element of the present claims is located at the proximal end of the claimed assembly, and "proximal of the fluid inlet."

Another important distinction is that the "semi-rigid support 73" of Long '938 is located inside the expandable sleeve 75, which is "filled with a conductive fluid." By contrast, the spring element of the present claims is located in a housing wherein it is "fluidically isolated from the tube lumen."

For all of the foregoing reasons, Long '938 fails to teach or suggest the claimed spring element, which the Examiner admits is missing from Boucher '773.

3. No Basis for Combining Boucher '773 with Long '938

As noted above, Long '938 fails to teach the claimed spring element that is missing from the teachings of Boucher '773. In addition, Applicants respectfully submit that there is no reason whatsoever, apart from impermissible hindsight, for combining the disparate teachings of these two completely differently-oriented references.

The Examiner has argued that "Boucher et al and Long are analogous art because they are from the same field of endeavor/problem solving area of balloon catheters." But, this argument ignores the completely different and unrelated objectives of these two references. Even if Boucher '773 and Long '938 were placed side-by-side, one of ordinary skill in this art would see no connection whatsoever between the "semi-rigid support 73" of Long '938 and the "stylet 52" of Boucher '773 in the absence of the teachings of this invention. This is the very essence of "hindsight."

4. Other Distinctions Between the Claimed Invention and the Prior Art

With regard to Claim 5, the Examiner argued that the "stylet 52" of Boucher '773 "is an active tensioning device." Applicants respectfully submit that, as used in this application, the term "active tensioning" means or at least implies a tensioning of the balloon element that occurs automatically without additional manual manipulation of the balloon tensioning device.

In Boucher '773, every step of tensioning and/or wrapping the balloon necessitates manual manipulation of stylet 52. By contrast, with the claimed embodiment of the present invention, because of the spring-activated rod member, the step of stopping fluid pressurization of the balloon or deflating the balloon automatically results in tensioning the balloon to reduce its profile. This automatic tensioning on deflation of the balloon can be extremely advantageous for a physician who does not have a third hand to manipulate the rod while also attending to other aspects of the medical procedure.

With regard to Claim 10, the Examiner argued that "stylet 52 is simply coupled to the distal end of the expandable element, not attached...." (citing col. 5, lines 63-65 of Boucher '773). But, this portion of Boucher '773 actually states that "the distal end of the stylet 52 is jointly (not "simply"!) coupled with the distal end of the inner catheter body 18 to the distal end of the expandable structure 56." This passage is best understood in light of the following description at col. 6, lines 8-12 of Boucher '773, discussing how the "torque caused by twisting the luer cap 24 is transmitted by stylet 52 to the distal ends of ... the expandable structure 56, which, as before described, are jointly coupled to the distal end of stylet 52." The transmission of torque by stylet 52 to the expandable structure 56 is possible only if stylet 52 is attached to structure 56.

With respect to Claims 24 and 106, the Examiner argued that Boucher '773 "teaches filling the cavity (80) left by deflating structure 56 with a filling material (88)." Boucher '773, however, does not teach that "the interior of the inflated balloon element is filled in situ with a cement material," as recited in the subject claims.

C. Prior Art Made of Record and Not Relied On

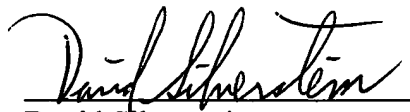
Applicants have duly noted the prior art the Examiner cited to make of record but which was not relied upon. The Examiner observed that these additional references "teach or disclose both claimed and unclaimed aspects of applicant's (sic) invention." Applicants respectfully submit, however, that the presently pending claims patentably distinguish over this additional prior art as well as the prior art on which the prior art rejection was based.

Applicants also call the Examiner's attention to the additional prior art cited in the Supplemental Information Disclosure Statement accompanying this Amendment and Response.

SUMMARY AND CONCLUSIONS

Accordingly, Applicants respectfully submit that Claims now pending in this application are in condition for allowance, and an early notification thereof is earnestly requested.

Respectfully submitted,



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